EXHIBIT A

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAUSCH & LOMB INCORPORATED & PF CONSUMER HEALTHCARE 1 LLC Plaintiffs, vs. SBH HOLDINGS LLC, Defendant	Civil Action No.: **20-cv-01463-GBW-CJB** **SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING** Rule 26(a)(2)(C)

Attorney for defendant SBH HOLDINGS LLC
Glenn A. Brown, Attorney at Law
727 N. Market Street #4
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Attorney for defendant SBH HOLDINGS LLC

Pro Hac Vice Counsel:

Frear Stephen Schmid
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Petaluma, CA 94952
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Thomas M. Freiburger
P.O. Box 1026
Tiburon, CA 94920
Tel: 415-435-0240
tfreiburger1@yahoo.com

Defendant SBH HOLDINGS LLC hereby discloses pursuant to Rule 26(a)(2)(C) its unretained expert Zac Denning. Zac Denning is currently employed by and been employed by defendant SBH Holding since 2004. Currently he has the job title Director, Scientific & Professional Affairs.

Zac Denning has not and never has been an employee of SBH who has regularly given expert testimony as an expert. He has not been retained to act as an expert for SBH in this matter but has formulated his expert opinions in the normal course of his ordinary duties as an employee of SBH and has formed those opinions in the context of his observations made as part of and in fulfillment of his duties as an employee for SBH. He has not been retained or specially employed to provide expert testimony nor do his duties regularly involve giving expert testimony. He has never testified or been retained as an expert in any other cases or matters.

OPINIONS AND FACTS

Plaintiff has asserted U.S. Patent Nos 6,660,297 and 8,603,522

this matter.

As a result of Mr. Denning's employment activities for the last 24 years plus, exclusive of any attorney client communications, he has formed the following expert opinions. He has concluded that a person reasonably skilled in the art pertaining to the claimed inventions in said patents, including himself as such a person, would not be able to determine the formulation of vitamin A as beta-carotene, vitamin C, vitamin E, zinc and copper of the present invention, particularly "vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof". The "substituted or supplemented with"

term appears in claim 19 of the '297 patent and claim 11 of the '522 patent. Exemplary claim 19 of the '297 patent recites:

> **19.** A composition comprising on a daily dosage basis:
>
> approximately 7 to 10 times the RDA of vitamin C;
> approximately 13 to 18 times the RDA of vitamin E;
> approximately 6 to 10 times the RDA of *vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof*;
> approximately 4 to 7 times the RDA of zinc; and
> at least 1.6 mg of copper and not more than approximately 2.4 mg copper into a suitable dosage form.

Mr. Denning is of the opinion based upon his work experience in the field of and knowledge of macular degeneration, the AREDS studies and his review of the subject patents that the description ("vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof") is so uncertain that no reasonable person skilled in the art upon reading the complete patent could determine how to formulate the required vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof. At the very least, he opines that much effort would be needed to determine a formulation and that effort would require undue, expensive, and time-consuming experimentation. His opinion is that zeaxanthine and lutein are not substitutes for beta-carotene in that they have different functions in the eye and go to different parts of the eye.

Dated :February 20,2024

/s/*Frear Stephen Schmid*

Frear Stephen Schmid

Attorney for defendant SBH HOLDINGS LL

CERTIFICATE OF SERVICE

I hereby certify that on Feb. 20,2024, copies of the foregoing were caused to be served upon the following plaintiffs' counsel via email:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014) Derek J. Fahnestock (#4705) 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 (302) 658- 9200

jblumenfeld@morrisnichols.com and dfahnestock@morrisnichols.com

Scott K. Reed ,Steven C. Kline, Monica Chou

VENABLE LLP 151 West 42nd Street, 49th Floor New York, NY 10036 (212) 307-5500 Attorneys for Plaintiff Bausch & Lomb

Dated :February 20,2024

/s/*Frear Stephen Schmid*

Frear Stephen Schmid

EXHIBIT B

Chou, Monica

From: Chou, Monica
Sent: Friday, February 23, 2024 3:12 PM
To: Frear Stephen Schmid; Jack Blumenfeld; Derek Fahnestock; Kline, Steven C.
Cc: Reed, Scott K.; Kaltman, Daniel H.
Subject: RE: SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING Rule 26(a)(2)(C)

Follow Up Flag: Follow up
Flag Status: Completed

Counsel,

In light of Magistrate Judge Burke's rejection of SBH's request for an extension of time including to serve all affirmative expert reports, the clear deficiencies in SBH's invalidity contentions and the undeniable fact that SBH bears the burden of proof (by clear and convincing evidence) on all invalidity allegations, we were surprised that the only expert disclosure of SBH was a Rule 26(a)(2)(C) Disclosure/Opinion of Unretained Expert Witness Zac Denning.

In any event,

1. Mr. Denning's disclosure is clearly inappropriate and inadequate under Rule 26(a)(2)(C) in view of Mr. Denning's deposition testimony and because it does not provide a sufficient summary of facts and opinions as required under Rule 26(a)(2)(C). Please immediately withdraw that disclosure.

2. In addition, please immediately confirm that SBH is withdrawing all other invalidity defenses (other than those set forth in Mr. Denning's disclosure - which is limited to enablement) and that SBH will not attempt to offer expert testimony on any other invalidity defense at any point in this litigation.

If SBH refuses to do so, please provide your availability for a meet and confer early next week so that the parties can proceed to trial under the current schedule as directed by Magistrate Judge Burke.

Best regards,

Monica Chou, Esq. | **Venable LLP**
t 212.218.2368 | f 212.307.5598
151 W. 42nd Street, 49th Floor, New York, NY 10036

MChou@Venable.com | www.Venable.com

From: Frear Stephen Schmid <frearschmid@aol.com>
Sent: Tuesday, February 20, 2024 7:41 PM
To: Jack Blumenfeld <jblumenfeld@morrisnichols.com>; Derek Fahnestock <dfahnestock@morrisnichols.com>; Kline, Steven C. <SCKline@Venable.com>; Chou, Monica <MChou@Venable.com>
Subject: SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING Rule 26(a)(2)(C)

Dear Counsel please see attached served hereby.

Very truly yours,

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Petaluma, CA 94952
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e-mail: frearschmid@aol.com

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EXHIBIT C

Chou, Monica

From: Frear Stephen Schmid <frearschmid@aol.com>
Sent: Wednesday, February 28, 2024 1:46 PM
To: Jack Blumenfeld; Derek Fahnestock; Kline, Steven C.; Chou, Monica
Cc: Reed, Scott K.; Kaltman, Daniel H.
Subject: Re: SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING Rule 26(a)(2)(C)

Follow Up Flag: Follow up
Flag Status: Completed

Hi Monica,

SBH strongly disagrees with plaintiffs' contentions/positions. Your conclusionary statements are not helpful to addressing the unfounded sweeping assertions. Without substantive guidance as to legal or factual basis for the assertions, we cannot at this time prepare for a meaningful discussion.

In any event, I am not available until Monday March 4 at the earliest. Also, I presume you expect Glenn to partake, but have not cc'd him, so I need to confirm his availability.

Thanks.

Very truly yours,

Frear Stephen Schmid
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Petaluma, CA 94952
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e-mail: frearschmid@aol.com

++++++++++++++++++++

On Wednesday, February 28, 2024 at 08:27:57 AM PST, Chou, Monica <mchou@venable.com> wrote:

Counsel,

We have not received a response on the below email yet. Please immediately provide your availability for a meet and confer this week, or alternatively, confirm that SBH unequivocally agrees with points 1 and 2 in the below email.

Best regards,

Monica Chou, Esq. | Venable LLP
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151 W. 42nd Street, 49th Floor, New York, NY 10036

MChou@Venable.com | www.Venable.com

From: Chou, Monica
Sent: Friday, February 23, 2024 3:12 PM
To: Frear Stephen Schmid <frearschmid@aol.com>; Jack Blumenfeld <jblumenfeld@morrisnichols.com>; Derek Fahnestock <dfahnestock@morrisnichols.com>; Kline, Steven C. <SCKline@Venable.com>
Cc: Scott K. Reed (SReed@Venable.com) <SReed@Venable.com>; Kaltman, Daniel H. <DHKaltman@Venable.com>
Subject: RE: SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING Rule 26(a)(2)(C)

Counsel,

In light of Magistrate Judge Burke's rejection of SBH's request for an extension of time including to serve all affirmative expert reports, the clear deficiencies in SBH's invalidity contentions and the undeniable fact that SBH bears the burden of proof (by clear and convincing evidence) on all invalidity allegations, we were surprised that the only expert disclosure of SBH was a Rule 26(a)(2)(C) Disclosure/Opinion of Unretained Expert Witness Zac Denning.

In any event,

1. Mr. Denning's disclosure is clearly inappropriate and inadequate under Rule 26(a)(2)(C) in view of Mr. Denning's deposition testimony and because it does not provide a sufficient summary of facts and opinions as required under Rule 26(a)(2)(C). Please immediately withdraw that disclosure.

2. In addition, please immediately confirm that SBH is withdrawing all other invalidity defenses (other than those set forth in Mr. Denning's disclosure - which is limited to enablement) and that SBH will not attempt to offer expert testimony on any other invalidity defense at any point in this litigation.

If SBH refuses to do so, please provide your availability for a meet and confer early next week so that the parties can proceed to trial under the current schedule as directed by Magistrate Judge Burke.

Best regards,

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MChou@Venable.com | www.Venable.com

From: Frear Stephen Schmid <frearschmid@aol.com>
Sent: Tuesday, February 20, 2024 7:41 PM
To: Jack Blumenfeld <jblumenfeld@morrisnichols.com>; Derek Fahnestock <dfahnestock@morrisnichols.com>; Kline, Steven C. <SCKline@Venable.com>; Chou, Monica <MChou@Venable.com>
Subject: SBH's DISCLOSURE/OPINION OF UNRETAINED EXPERT WITNESS ZAC DENNING Rule 26(a)(2)(C)

Caution: External Email

Dear Counsel please see attached served hereby.

Very truly yours,

Frear Stephen Schmid

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Petaluma, CA 94952

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++++++++++++++++++++

EXHIBIT D

Chou, Monica

From: Kline, Steven C.
Sent: Wednesday, November 22, 2023 3:19 PM
To: Frear Stephen Schmid; Jack Blumenfeld; Derek Fahnestock; Chou, Monica
Cc: Thomas Freiburger; glenn brown; Venable PreserVision
Subject: Bausch Lomb v. SBH

Counsel,

We write regarding SBH's Final Invalidity Contentions served on November 15, 2023. Plaintiffs believe SBH's Final Invalidity Contentions are deficient in several respects.

With regard to SBH's contention that the '522 Patent is invalid for obviousness-type double patenting, SBH provides little more than a conclusory statement that the '522 patent is invalid for double patenting over the '297 patent. Analysis of OTDP involves two steps, each of which must be performed on a claim-by-claim basis: "[f]irst, the court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *UCB, Inc. v. Accord Healthcare, Inc.,* 890 F.3d 1313, 1323 (Fed. Cir. 2018) (internal quotations omitted). SBH's contentions fail to provide any claim by claim analysis, nor an analysis on the patentably distinct inquiry.

With regard to SBH's contentions of obviousness of the '297 Patent and '522 Patent, there is no explanation as to: (1) what specifically in the listed references render the asserted claims of the patents invalid as obvious, (2) the specific combination of references it is asserting, or (3) why a POSA would be motivated to combine the teachings of the prior art. For each of its invalidity theories, SBH "should include supporting evidence." *Cleveland Medical Devices, Inc. v. ResMed Inc.,* 1-22-cv-00794 (DDE) (J. Williams), D.I. 177. SBH's explanation "should include identification of the claim element(s) disclosed by each reference in the combination." *Id.; See also Astellas Pharma Inc. et al v. Sandoz Inc. et al,* 1-20-cv-01589 (DDE) (J. Burke), D.I. 343 (ordering that Defendant must "provide fulsome detail regarding the obviousness arguments for those specific invalidity *combinations*") (emphasis added).

Please advise whether SBH will promptly supplement its Final Invalidity Contentions to address these deficiencies.

Sincerely,
Steve

Steven C. Kline, Esq. | **Venable LLP**
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EXHIBIT E

Chou, Monica

From: Kline, Steven C.
Sent: Thursday, December 14, 2023 1:03 PM
To: Thomas Freiburger; Frear Stephen Schmid; glenn brown
Cc: Derek Fahnestock; Jack Blumenfeld; Venable PreserVision
Subject: RE: Bausch & Lomb . v. SBH Holdings, LLC, No. 20-cv-01463

Follow Up Flag: Follow up
Flag Status: Completed

Counsel,

We write regarding SBH's Supplemental Invalidity Contentions served on December 5, 2023. Although SBH added two sentences on page 2: incorporating by reference SBH's Motion for Judgement on the Pleadings and attaching portions as an Appendix, SBH has not addressed Bausch's identified deficiencies regarding obviousness that were communicated in my email on November 22, 2023. Please advise whether SBH will promptly supplement its Invalidity Contentions to address those deficiencies. Bausch reserves the right to move to preclude SBH as to any arguments that are not disclosed in its Supplemental Invalidity Contentions.

Sincerely,
Steve

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SCKline@Venable.com | www.Venable.com

From: Thomas Freiburger <tfreiburger1@yahoo.com>
Sent: Tuesday, December 5, 2023 7:01 PM
To: Kline, Steven C. <SCKline@Venable.com>
Cc: Derek Fahnestock <dfahnestock@morrisnichols.com>; Jack Blumenfeld <jblumenfeld@morrisnichols.com>
Subject: Re: Bausch & Lomb . v. SBH Holdings, LLC, No. 20-cv-01463

Counsel:

Please see the attached Supplemented Final Invalidity Contentions.

Regards,

Tom Freiburger

EXHIBIT F

REDACTED

IN ITS

ENTIRETY

EXHIBIT G

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAUSCH & LOMB INCORPORATED & PF CONSUMER HEALTHCARE 1 LLC Plaintiffs, vs. SBH HOLDINGS LLC, Defendant	Civil Action No.: 20-1463 (GBW)(CJB)

SBH'S SUPPLEMENTED FINAL INVALIDITY CONTENTIONS REGARDING BAUSCH & LOMB'S PATENTS

Pursuant to the Court's Scheduling Order (D.I. 28) and the Court's Default Standard for Discovery, including Discovery of Electronically Stored Information Paragraph 4(c) Defendant SBH hereby provides the following Final Invalidity Contentions ("Contentions") concerning Plaintiffs' U.S. Patents Nos. 6,660,297 ("the '297 patent") and 8,603,522 ("the '522 patent").

These Contentions are based on the information presently and reasonably known to Defendant as discovery may reveal more grounds. Moreover, the Court has not yet construed any of the asserted claims of the '297 and '522 patents, and construed breadth will likely affect validity. In addition, Defendant's investigation into Plaintiffs' '297 and '522 patents continues and Defendant reserves the right to rely on further production by Plaintiffs, expert discovery and/or testimony to support invalidity of the '297 and '522 patents. Defendant provides these Contentions without prejudice to its right to modify, amend, or otherwise supplement them, as provided in the Federal Rules of Civil Procedure, the Court's Scheduling Orders, and the Local Rules of the United States District Court for the District of Delaware.

Plaintiffs have asserted against Defendant claims 19, 24, 31 and 32 of the '297 patent (post-reexamination) and claims 1, 4, 5, 6, 8, 11, 15, 16 and 20 of the '522 patent.

Invalidity of the '522 Patent

Defendant SBH contends the '522 patent is invalid for obviousness-type double patenting, based on the prior '297 patent, over which the claims of the '522 patent are obvious. The claims of the '522 patent are directed to a method of treatment using the compositions defined in the claims of the '297 patent. The '522 patent did not have any terminal disclaimer in regard to the term of the '297 patent, thus the '522 patent is and has been invalid since its issuance. Federal Circuit law on obviousness-type double patenting is compelling in this regard. See, for example, *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir. 2014); *Sun Pharmaceutical Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010); and *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373 (Fed. Cir. 2003). This line of Federal Circuit decisions deals with precisely the same issue as the current case, and leaves no doubt that the '522 patent is invalid. Currently SBH incorporates by reference its Motion for Judgment on the Pleadings, currently before this Court and filed April 4, 2023, with supporting brief, as to support for its position on invalidity of the '522 patent. Relevant portions (cover sheet to page 11) are attached as Appendix 1 to this brief.

Invalidity of Claims of the '297 Patent

At least claims 19, 24, 31 and 32 of the '297 patent are invalid.

Claims 19 and 24

Claim 19 has the vague and ambiguous language "6 to 10 times the RDA of vitamin A in the form of beta-carotene, *substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof*." Claim 24 (added in the reexamination of the patent) depends from claim 19 and calls for zinc oxide, copper oxide.

Claim 19's wording does not comply with the patent statute, §112, which requires that a claim must "inform, with reasonable certainty, those skilled in the art about the scope of the invention." Claim 19's wording does not give guidance as to how much lutein or zeaxanthine would be required to replace, partially replace, or "supplement" the beta-carotene, which is to be 6 to 10 times the RDA of vitamin A as beta-carotene, i.e. 17.2 mg to 28 mg as defined in the patent's description. Claim 19 also fails to enable one skilled in the art to make and use the invention, as supported below.

If one were to "substitute" some of the beta-carotene, the patent gives no guidance as to how much lutein and/or zeaxanthine would be required to be equivalent to the beta-carotene deleted. For example, if the beta-carotene were included in an amount below the lowest level, 17.2 mg, then one can only guess how much zeaxanthine or lutein would be required.

Zeaxanthine is described in the specification with an enormous range of .04 mg to 40 mg. The upper limit is 1000 times the lower limit. Absolutely no guidance is given as to equivalency of zeaxanthine or lutein amounts to beta-carotene amounts, and none was available in the industry or literature at the time of filing the application in 2021.

For definiteness to advise the public as to what would be an infringement, the patent would have had to define, for a milligram of beta-carotene, what would be the equivalent amount

of zeaxanthine or lutein. Examples were needed, or a table of effective amounts showing the interplay of amounts of all three components, beta-carotene, zeaxanthine and lutein.

Moreover, the '297 specification does not state, suggest or imply that all beta-carotene could or should be eliminated. Although not specifically stated in the description or claims, it is hinted in the description that beta-carotene might be reduced to below 20 mg per day to reduce health risk to smokers (not eliminated). The AREDS 1 trial, on which the '297 patent is based, indicated beta-carotene as the source of vitamin A. Still further, Plaintiff confirmed in the file history the claims were limited to including beta-carotene, and distinguishing from the Gorsek prior patent reference, arguing the difference "in the amount and type of vitamin A (Gorsek's natural carotenoids vs. applicants' beta carotene)". Those natural carotenoids in Gorsek included lutein and zeaxanthine. These arguments were made for "the invention" in general, and thus were referring to all claims before the examiner.

In addition, claims 19 and 24 fail to meet the requirement of §112 of the patent statute requiring enablement of the invention. With no information regarding substitution amounts which might be equivalent to beta-carotene, claims 19 and 24 considered along with the description, failed to provide sufficient information for one of skill in the art to make and use the invention of those claims without undue experimentation. Manifestly undue experimentation would be required, in the form of long-term clinical trials with lutein and zeaxanthine, as compared with trials employing beta-carotene.

In its decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 134 S.Ct. 2120 (2014), the Supreme Court changed the standard for finding indefiniteness based on ambiguity of claims. The required level of definiteness was increased, and since that decision a patent claim must be understandable with "reasonable certainty", lest it will be found unenforceable or

invalid. The Court specifically rejected the prior standard which included the notion that the claim meaning may be "one over which reasonable persons will disagree." The '297 patent's reexamined claims 19 and 24 do not sufficiently state the meaning and bounds of the claim with "reasonable certainty", and fail to provide "objective boundaries" as to what would constitute an infringement, per the *Nautilus* decision. Claims 19 and 24 are invalid, if they are not interpreted to strictly require beta-carotene in the range stated in the claim. The fact is, claim 19 as originally filed did strictly require beta-carotene, without any substituting or supplementing. The "substituted or supplemented" wording was only in a dependent claim, throughout prosecution of the application until allowance of claims. Only after the examiner objected to that dependent claim as adding nothing to claim 19's limitation (undoubtedly based on the vague term), did Plaintiff add the "substituted or supplemented" wording into claim 19. Note that at all times dependent application claim 10 ("substituted or supplemented" . . .) fully incorporated all elements of application claim 1 (requiring beta-carotene).

If Plaintiff's purported understanding of patent claim 19 were correct, then application claim 10 would be infringed by a product that did not infringe application claim 1 --- such a product would be one without beta-carotene. By law this is impossible. Chisum §8.06[5], and *Eltech Systems Corp. v. PPG Industries*, 710 F. Supp. 622, 634 (Fed. Cir. 1990): "By definition, if the claim to which the dependent claim refers is not infringed, the dependent claim cannot be infringed, as a matter of law."

Although the above relates in part to the meaning of the claims, the contrapositive holds true. The Court has not construed the claims, but if claim 19's beta-carotene is found not required, then the claims are invalid as indefinite.

Claim 19 and the other asserted claims of the '297 patent are invalid under §112 further because they do not enable any person of skill to make and use the invention. Plaintiff's statement in its briefs that any POSA would be able "to prepare compositions with lutein, zeaxanthine, etc." misses the point; no one would have any idea from the description how much of either or both should be used to achieve the health benefit desired (as achieved by 17.2 to 28 mg beta-carotene). Zeaxanthine's range has a factor of 1000, covering every possibility. It appears Plaintiff had no idea how much zeaxanthine (or lutein) could be effective, at the time of filing. The specification simply invites a POSA to try any of a huge myriad of combinations. The recent Supreme Court decision *Amgen Inc. v. Sanofi*, 598 U.S. ___ (May 18, 2023, 21-757) is squarely on point, involving patents on antibodies engineered to reduce LDL cholesterol. Amgen claimed an entire genus of possible antibodies that might work to perform two required functions, with 26 antibodies specifically identified. The Court found enablement lacking:

> Think about it this way. "Imagine a combination lock with 100 tumblers, each of which can be set to 20 different positions" . . . "Through trial and error, imagine that an inventor finds and discloses 26 different successful lock combinations." *Ibid*. But imagine, too "that the inventor tries to claim much more, namely all successful combinations" . . . Sure enough, that kind of "roadmap" would produce functional combinations. But it would not enable others to make and use functional combinations; it would instead leave them to "random trial and error discovery."

The current case is similar and fails the test of *Amgen v. Sanofi*, but is even more lacking in enablement. The '297 patent fails to even give any example of a "successful combination" with amounts of beta-carotene, lutein and/or zeaxanthine. A POSA is left completely in the dark as to what could work among many millions of possible combinations.

The logic of the Supreme Court in *Amgen v. Sanofi* is also applicable to indefiniteness with millions of combinations among the three components, the claims and specification give not a hint of what is the invention being claimed.

Claims 31 and 32

Claim 31, along with dependent claim 32, was added by amendment in the reexamination of the '297 patent.

As explained above, claim 19 is invalid, or at the very least, if it is to be interpreted in a way as to be valid, it must require beta-carotene.

Claims 31 and 32 do not require beta-carotene, but simply set forth the inclusion of both lutein and zeaxanthine, in the same very wide ranges given in the description. Therefore they are broader than claim 19; they constitute a broadening of claim 19, since they would cover compositions that would not be covered by any claim of the '297 patent as originally issued (note that claim 19 was not modified by reexamination, except to put an upper limit on copper). Such broadening of the scope of claims in an *inter partes* reexamination is contrary to law. As quoted by the examiner in the '297 reexamination,

> 35 U.S.C. 314(a) states that "no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted" in an *Inter Partes* reexamination proceeding. A claim presented in a reexamination "enlarges the scope" of the patent claims where the claim is broader than the claims of the patent. A claim is broadened if its broader in any one respect, even thought it may be narrower in other respects.

Although the examiner failed to catch this, claim 31 is a broader claim than any claim in the original '297 patent in that claim 31 does not mention beta-carotene. Nor does claim 32.

Claim 31 and dependent claim 32 were therefore improperly allowed on reexamination and are invalid.

Claim 31 not only impermissibly broadens the claim coverage of the '297 patent, but also claims an embodiment not supported by the specification, which supports only claims requiring beta-carotene. This also violates §112 and adds further to invalidity.

Obviousness Grounds of Invalidity, '297 and '522 Patents

In addition to the above, both patents are invalid for obviousness over prior art. Relevant documents are as follows:

Lange Publication WO 2001/019383, a PCT filing from U.S. app. 09/397,472 filed September 19, 1999. The PCT was filed March 22, 2001.

Garnet Patent No. 5,747,544, issued May 5, 1998.

These references, in combination with references cited in the prosecution of the '297 and '522 patents, render invalid all claims at issue. In particular, those cited references include:

Gorsek Pat. No. 6,103,756

Lattange Pat. No. 5,075,116

Newsome, D.A., Oral Zinc in Macular Degeneration, Arch. Ophthalmol., Vol. 106, February 1988, pp. 192-198

Riley Pat. No. 5,976,568

Combinations of the above references would show all asserted claims to have been obvious to a person of ordinary skill in the art.

In addition, Federal Court law mandates that the '522 patent claims are invalid for obviousness-type double patenting over the '297 patent.

Dated: December 5, 2023

/s/ Thomas M. Freiburger
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Attorneys for Defendant SBH Holdings LLC

CERTIFICATE OF SERVICE

I hereby certify that on December 5, 2023, copies of the foregoing, including Appendix 1, were caused to be served upon the following in the manner indicated:

Steven C. Kline, Esq.
Venable LLP
1290 Avenue of the Americas, 20th Floor
New York, NY 10104
Attorneys for Plaintiffs

VIA ELECTRONIC MAIL

Derek J. Fahnestock, Esq.
Jack B. Blumenfeld, Esq.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
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Wilmington, DE 19899
Attorneys for Plaintiffs

VIA ELECTRONIC MAIL

/s/ Thomas M. Freiburger
Thomas M. Freiburger

APPENDIX 1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAUSCH & LOMB INCORPORATED & PF CONSUMER HEALTHCARE 1 LLC Plaintiffs, vs. SBH HOLDINGS LLC, Defendant	Civil Action No.: **20-cv-01463-GBW-CJB** **MOTION FOR JUDGMENT ON THE PLEADINGS**

Attorney for defendant SBH HOLDINGS LLC
Glenn A. Brown, Attorney at Law
727 N. Market Street #4
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Nature and stage of the proceedings.

This is plaintiffs' second lawsuit against defendant alleging infringement of the same patents, U.S. Patents Nos. 6,660,297 and 8,605,522. The Plaintiffs (hereinafter Plaintiff) dismissed its first complaint against defendant in the Western District of New York after forcing defendant to file a motion to dismiss for lack of venue. This patent case is in the fact discovery stage. Joint Claim Construction Brief due May 23, 2023.

Summary of argument.

1. The '522 patent is invalid due to double patenting over the '297 patent. 35 U.S.C. §101, *Abbvie Inc. v. Mathilda & Terence Kennedy Inst.*, 764 F.3d 1366 (Fed Cir. 2014).

2. The asserted claims of the '297 patent require beta-carotene, or are invalid. The file history and the specification confirm beta-carotene is required. Further, claim 19 is vague and indefinite under 35 U.S.C. § 112(d) and *Nautilus v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).

3. '297 claims 31 and 32 are invalid as broadening of claims in *inter partes* reexamination, counter to 35 U.S.C. 314(a). Claims 31 and 32 do not recite beta-carotene.

4. This is a motion for judgment on the pleadings. The granting of this motion will completely dispose of this case. The '522 patent is invalid as a matter of law. All asserted claims of the '297 patent are either invalid or not infringed as a matter of law. For purposes of this motion, no facts are in dispute, as all facts are part of the PTO files and judicially noticeable Thus, the applicable law is the determining factor. This motion is accompanied by the Declaration of Thomas Freiburger, verifying true and correct copies of relevant extracts from the PTO files relative to the subject patents and the relevant exerpt from plaintiff's Infringement Contentions.

5. The grounds for invalidity of the '522 patent are separate and independent from those for invalidity or unenforceability of the '297 patent claims.

Statement of facts.[1]

1. The asserted '297 patent claims are composition claims on a treatment for AMD. The '522 patent claims are directed to a method of use of those same compositions in treating AMD. See '297 patent, '522 patent and '297 reexamination certificate, Exhs. 1, 2 and 3.

2. Plaintiff filed a first continuation from the '297 patent application on August 15, 2003, application No. 10/641,668 ('668 application), later abandoned, from which the '522 patent application was filed as a further continuation January 13, 2005. Exh. 2, cover sheet.

3. No terminal disclaimer was filed in the '297 patent prosecution, PTO records. The '522 patent was not filed as a result of or following any terminal disclaimer. PTO records.

4. The '297 patent application and the '522 patent application, original claims, required beta-carotene in all independent claims; the phrase "substituted or supplemented with . . . " was only present in dependent claims. Exhs. 4, 11. By amendment, prompted by examiner's comment, the phrase was moved into independent claims. Exhs. 8, 9.

5. Plaintiff argued the importance of including beta-carotene in the composition, as opposed to carotenoids used in prior art, in urging the examiner to allow the claims. Exh. 10.

6. '297 patent claims 31 and 32 were added in reexamination. Exh. 3.

7. Plaintiff made the judicial admission in its Infringement Contentions that the accused products do not contain beta carotene. Exh. 17.

ARGUMENT

I. MOTION ON THE PLEADING MUST BE GRANTED AS A MATTER OF LAW

[1] See attached declaration of Thomas Freiburger confirming all exhibits to this brief are true and accurate copies of PTO records (or of Plaintiff's Infringement Contentions).

Pursuant to F.R.C.P. 12(c), the movant for judgment on the pleadings must establish: 1) that no material issue of fact remains to be resolved; and 2) that he is entitled to judgment as a matter of law. *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). In resolving such motions, that Court may consider: 1) those matters referenced in the complaint; 2) matters of public record; and 3) matters integral to or upon which a plaintiff's claim is based. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). To that end defendant requests judicial notice of Exhibits 1 through 16 of which are matters of public record on file with the USPTO, and of Exhibit 17, a judicial admission by plaintiff in its Infringement Contentions dated October 31, 2022 that the accused products do not contain beta carotene. DKT 50. Judicial notice under Rule 201 permits a court to judicially notice an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id.* See *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital,* 432 F. 396, 401 n.15 (3d Cir. 2006). For the reasons set forth below, this motion for judgment on the pleadings should be granted.

II. PATENT 8,603,522 IS INVALID

A. Double Patenting invalidates the '522 patent

35 U.S.C. §101 and court interpretations thereof prohibit double patenting. The courts have long recognized the principle of double patenting, ever since the inception of the patent laws. See *Abbvie, Inc. v. Mathilda & Terence Kennedy Inst. Rheumatology Trust*, 764 F.3d 1366 at 1372 (Fed. Cir. 2014), citing a 1819 Justice Story opinion:

It cannot be, that a patentee can have in use at the same time two valid patents for the same

> invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century . . . If this proceeding could obtain countenance, it would completely destroy the whole consideration derived by the public for the grant of the patent, . . . the right to use the invention at the expiration of the term specified in the original grant.

The USPTO and courts recognize two types of double patenting: same-invention double patenting, often called statutory double patenting; and obviousness-type double patenting. (OTDP) MPEP §804. Under either of these doctrines a later-expiring patent is invalid for double patenting [see cases cited below], unless a terminal disclaimer has been filed (disclaiming term of second patent that would extend beyond the first).

All continuation, continuation-in-part or divisional applications expire on the same date as the "parent" or original application, since the parent application's priority date is the priority date for all such further related applications. The term extends 20 years from that date. 35 U.S.C. § 154(a)(2). Thus, the expiration date of the continuation application in the instant case, the '522 patent, was the same as that of the '297 patent, March 23, 2021. In this case, the '522 patent was improperly granted a term adjustment under 35 U.S.C. §154, due to supposed delays caused by the patent office. This very long term adjustment is the reason the '522 patent is allegedly still alive. Plaintiff was not entitled to this term adjustment.

B. <u>Obviousness-Type (Nonstatutory) Double Patenting (OTDP)</u>

The '522 patent claims amount to OTDP over the '297 patent, and are invalid.

The original '297 application had composition claims directed to a formula for AMD (age-related macular degeneration) treatment, and also had claims directed to method of treatment of AMD using that composition. Those claims coexisted in the first patent application, without objection. Exhs. 4, 5. The examiner correctly treated them as essentially the same invention, or obvious variants of each other, rather than independent and distinct inventions. Plaintiff at its

own volition carved out method claims from the original application and filed them in a continuation application that ultimately became the '522 patent. (See '522 patent, Exh. 2)

Federal Circuit cases are squarely in point and address the exact same issue as involved here regarding invalidity for double patenting. In *Sun Pharmaceutical Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010) the court held that "a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use" (611 F.3d at 1385), citing its earlier decisions in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), and *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373 (Fed. Cir. 2003). *Abbvie, Inc., supra*, is in agreement. In all these cases the issues were similar: an earlier patent claimed a composition, and included in the specification a description of the efficacy of the composition to treat a particular condition; and the later patent (or later-expiring patent) claimed a method of using that compound for that same treatment described in the specification of the first patent. In *Sun*, the patent owner Lilly had a first patent that described and claimed a drug called gemcitabine, and its effectiveness against certain viruses. That '614 patent (U.S. PN 4,808,614) did not claim the use of gemcitabine against cancer, but the specification stated that in addition to other antiviral utility of gemcitabine, the inventors had found effectiveness against cancer. The later Lilly patent (U.S. PN 5,464,826) application[2] was filed on the same day as the '614 patent application, but due to differing priority dates, the '826 patent would expire two and a half years after the '614 patent. Lilly did not file a terminal disclaimer regarding the '826 (later) patent.

Although the '614 patent had no claims to the method of use of gemcitabine in treating

[2]All references herein to "the '826 patent application", "the '522 patent application", "the '297 patent application", etc. refer to the patent number, rather than the application serial number, unless otherwise indicated.

cancer, its specification did describe use of gemcitabine in treatment of cancer. The second patent, the '826 patent, did have method claims for treatment of cancer using gemcitabine. The Federal Circuit Court held that the asserted method of treatment claims of the '826 patent were invalid over the composition claims of the '614 patent, for OTDP. The Court looked to the '614 patent specification and found and specifically repeated the specification's statements regarding efficacy of gemcitabine against cancers. As stated in *Sun, supra,* at 1387:

> Thus, the holding of *Geneva* and *Pfizer*, that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use," extends to any and all such uses disclosed in the specification of the earlier patent. *Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385-86. Indeed, as both cases recognized,
> [i]t would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, *setting out at length in the specification* the *useful purposes* of such composition, . . . and then prevent the public from making any beneficial use of such product by securing patents *upon each of the uses* to which it may be adapted. [Emphasis original]

Precisely the same facts and issues are presented here. The '297 patent has claims to a composition for treating AMD. The '297 patent shares the same description as the '522 patent, describing the efficacy of the composition against AMD. Accordingly, the claims of the '522 patent are not patentably distinct from those of the '297 patent, the case law removing any doubt that the claims of the '522 patent amount to OTDP, and those claims are invalid according to the *Sun/Pfizer/Geneva/ Abbvie* line of cases. As in *Sun*, the Plaintiff herein did not file a terminal disclaimer with respect to the '522 patent, as it should have. Each '522 claim describes a method for treating AMD using the formula claimed and described in the '297 patent.[3]

The Plaintiff itself in fact pointed out the equivalence between the claims of the two patents,

[3] Quantities expressed as RDA multiples in some patent claims are equivalent to component weights stated in other claims as confirmed in the specification (Exh. 1:cols 5-6). These are pre-2016 revisions to RDAs.

in its final argument to the examiner on July 31, 2013. After eight years of prosecution of the '522 patent application, without success, Plaintiff B&L argued to the examiner:

> Claims 4 ['522 patent claim 1] and 26 ['522 patent claim 8] are amended and now includes language common to composition claims of family related U.S. Patent No. 6,660,297 that was subject to Inter-*partes* Reexamination in the United States Patent and Trademark Office. The Reexamination is identified by Control No. 95/000,301, which has been completed. A Reexamination Certificate was issued on April 30, 2013, a copy of which is attached to this Amendment.
> New method claim 29 ['522 patent claim 11] is consistent with reexamination composition claim 19.
> New claim 34 ['522 patent claim 16] is consistent with reexamination composition claim 31.

Based on this the examiner allowed the '522 patent claims, clearly agreeing the presented claims were equivalent in scope to those of the '297 patent, which had been confirmed (as amended) by reexamination. (Exh. 3). He directly allowed the '522 claims after Plaintiff made the above statements. Exh. 12. He should have rejected the claims, however, for OTDP and failing that, Plaintiff should have filed a terminal disclaimer in any event. Neither occurred.

As an example, the following is a comparison of a '522 method claim and a '297 composition claim, which were argued by Plaintiff as equivalent:

'522 Patent Claim 11:

> 11. A method for treating visual acuity loss in persons with early age-related macular degeneration, the method comprising administering a daily dosage composition comprising:
> approximately 7 to 10 times the RDA of vitamin C;
> approximately 13 to 18 times the RDA of vitamin E,
> approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof;
> approximately 4 to 7 times the RDA of zinc; and at least 1.6 mg and not more than approximately 2.4 mg copper.

'297 (Rexamined) Claim 19:

> 19. A composition comprising on a daily dosage basis:
> approximately 7 to 10 times the RDA of vitamin C;
> approximately 13 to 18 times the RDA of vitamin E;
> approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof;

approximately 4 to 7 times the RDA of zinc; and at least 1.6 mg of copper.

C. The '522 Term Adjustment Under §154 Does Not Overcome the OTDP Invalidity.

The '522 patent's term adjustment, granted mechanically by the PTO, cannot revive invalid claims. By the cited case law, the 20 claims of the '522 patent did not simply expire along with the expiration of the '297 patent; they were invalid from the moment of issuance. The purpose of the §154 term adjustment is to compensate for patent office delays in the prosecution of an application, not to revive an invalid patent.

Addressing the patent at issue in *Abbvie, supra,* which had such a purported term adjustment, an additional term of over two years, the *Abbvie* court stated:

> When such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variations thereof) does not receive an undue patent extension. (764 F.3d at 1373)

Holding the patent invalid for OTDP, the *Abbvie* court further cited the decision in *Gilead SCIS, Inc. v. Netco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), reaffirming the decision in *Gilead*. See also *Boehringer Ingelheim v. Barr Labs,* 592 F.3d 1340, 1346 (Fed. Cir. 2010):

> The doctrine of obviousness-type double patenting is an important check on improper extension of patent rights through the use of divisional and continuation applications . . .

As set forth in MPEP §804 and as discussed above, a terminal disclaimer can be filed by an applicant in the case of OTDP. By this disclaimer the applicant/patentee disclaims the period of a new patent that would extend beyond the expiration date of a first patent, owned or controlled by the same party. An examiner in the case of OTDP will make a rejection to that effect during prosecution, and the applicant responds with a terminal disclaimer so that a patent on that application cannot extend beyond the expiration date of an earlier patent. Often an examiner is mistaken in failing to make a double patenting rejection, and if the applicant does not file a

terminal disclaimer, the second patent then is invalid for lack of that disclaimer.[4]

Although the '522 patent was granted a term adjustment under 35 U.S.C. §154(b), such a term adjustment cannot apply in this case of double patenting, as confirmed with in *Abbvie*, *supra*. Additional case law supports this, differentiating §154(b) adjustments from §156 extensions. See *Novartis AG v. Ezra Ventures LLC* 909 F.3d 1367 (Fed. Cir. 2018); and *Magna Elecs., Inc. v. TRW Auto. Holdings Corp.* No. 1:12-cv-654 (USDC W. D. Mich.) Dec 10, 2015. *Novartis* concerned a patent term extension (PTE) under §156, basically to compensate for FDA delays on drug approvals, not patent office prosecution delays. The Federal Circuit, however, clearly distinguished PTE under §156 from patent term adjustments (PTA) under §154(b). A PTE (*Novartis*) can be enforceable even if a terminal disclaimer has been made --- although the patentee has disclaimed the last part of the patent term, this is overcome by the §156 term extension. At 909 F.3d 1373-1374, the court explained

> the contrast between §156 for PTE with the language of §154 for patent term adjustments: §154 "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays," but §156 contains "no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch-Waxman extensions."

Having made that distinction, the Federal Circuit Court in *Novartis* stated:

> For example, if a patent, under its original expiration date without a PTE [term extension under §156], should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court's obviousness-type double patenting case law would apply, and the patent could be invalidated [Emphasis added].

The court thus confirms that if there were OTDP in a PTA case (not a PTE case) and if no

[4] In the case of "same invention" type double patenting, the claims are claiming the same thing, with identical scope (if not the exact same wording), and there is no cure for that situation. A terminal disclaimer will not help. The focus here is on obviousness-type double patenting, sometimes referred to in Federal Court decisions as "OTDP".

terminal disclaimer were filed but should have been, the double patenting case law will apply, invalidating the patent. This is squarely in accord with *Abbvie, supra*.

That law applies here. The '522 patent application did not have a terminal disclaimer, but should have had one. The '522 examiner, (different from the '297 patent examiner) should have required the disclaimer, but failing that the Plaintiff should have filed one. In fact, it is somewhat difficult to believe that Plaintiff, with all its in-house and outside attorneys, and much previous litigation over these patents, could not have been aware of this line of case law, highlighted in notable Federal Circuit pharmaceutical decisions in 2003, 2008 and 2010 as reviewed above, all prior to the close of prosecution of the '522 patent.

D. Retroactive Terminal Disclaimer

Although a terminal disclaimer can be filed after issuance of a patent, it is not effective after the original patent has expired, to overcome OTDP invalidity, thus could not help Plaintiff now. See *Boehringer Ingelheim, supra*, which is squarely on point.

E. The '522 patent is Not Protected by the "Safe Harbor" of 35 U.S.C. §121

The purpose of the "safe harbor" provision of 35 U.S.C. § 121 is to prevent unfairness — if, in a patent examiner's opinion, two or more distinct inventions are represented by different claims, and the examiner thus makes a restriction requirement requiring the applicant to choose the claims of only one invention and file a divisional (if desired) on the other claims, it would be unfair to allow a later challenge to the second patent (or the first patent) on the basis of OTDP. That rationale does not apply here, since the filing of the '522 patent application was not the result of an examiner's restriction requirement in an earlier application. The application leading to the '522 patent was a continuation of application Serial No. 10/641,668, which was a continuation of the '297 patent [See '522 patent, Exh. 2]. Interestingly, the examiner in the

second application, the '668 application, did make a double patenting rejection, stating that method of use claims in '668 amounted to OTDP over the '297 patent composition claims. This may have influenced Plaintiff's decision to abandon that application, without response[5], in favor of a further continuation that became the '522 patent. Exhs. 6, 7.

Plaintiff's application leading to the '522 patent was not a divisional from the '297 patent, nor from the abandoned '668 application, nor was any application filed after a restriction requirement in the '522 patent application. Thus, no "safe harbor" is afforded Plaintiff. See *Pfizer Inc*, *supra* and *Geneva, supra* at 1378.

III. ASSSERTED CLAIMS 19, 24, 31 AND 32 OF THE '297 PATENT ARE NOT INFRINGED AND/OR ARE INVALID

The '297 patent is not applicable to Defendant's products, which lack beta-carotene. The plaintiff in its Initial Infringement Contentions has judicially admitted that defendant's products do not contain beta-carotene. Exh. 17, Dkt. 50, col.1=claim19; col.2=Defendant's products.

A. All original claims of Plaintiff's applications required beta-carotene unqualifiedly.

The '297 patent application, '668 application and '522 patent application (Exhs. 4, 11) had beta-carotene required in all independent claims. The term "substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof" was not included and was present only in several dependent claims. Since a dependent claim incorporates all limitations of a main claim to which it refers, all claims of the application required beta-carotene, including those reciting "substituted or supplemented with . . . " See 35 USC § 112(d).

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[5]The examiner in the '688 application also rejected the claims as not enabling "prevention" of AMD, but that could have been remedied by removing the word "prevent" from the claims. Regarding double patenting, the examiner stated "The instant claims now define that the compositions are intended to be used for treating macular degeneration. It would have [been] obvious to one of ordinary skill in the art to use a retinal health composition to treat a retinal condition to achieve the same expected results of treating or stabilizing such a condition."

EXHIBIT H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CLEVELAND MEDICAL DEVICES INC., Plaintiff, v. RESMED INC., Defendant.	C.A. No. 22-794-GBW

ORDER

At Wilmington, this 20th day of October, for the reasons stated during the October 18, 2023 teleconference,

IT IS HEREBY ORDERED that:

1. Plaintiff's Motion to Compel Defendant to limit asserted prior art references in its Initial Invalidity Contentions to ten (10) references is **GRANTED.** On March 9, 2023, the Court issued an Oral Order, D.I. 56, requiring the parties to conform their contentions to the per-patent cap of ten references pursuant to the Court's Scheduling Order, D.I. 40. While Defendant amended its initial invalidity contentions for the '269 Patent shortly thereafter, Defendant's Contentions continued to cite over twenty (20) references. *See generally* D.I. 164-1, D.I. 164-2. According to Defendant, these additional cited references were "background prior art references to explain the state of the art at the time of the invention." D.I. 169 at 2. While Defendant contends that it "went the extra mile by providing those background references in its invalidity charts," the Court does not judge the sufficiency of invalidity contentions solely on the volume of information provided.

See id. Rather, the Court expects Defendant to identify its invalidity theories with specificity by noting which of the ten (10) prior art references support each theory and why. By citing language from a multiplicity of "background" sources, Defendant has shifted to Plaintiff the burden of sorting through 200 pages of materials and speculating as to Defendant's invalidity theories. In doing so, Defendant has failed to provide adequate notice. Thus, Defendant is ordered to amend its Initial Invalidity Contentions to assert no more than ten (10) prior art references. However, Defendant's request to treat *each* of the four (4) prior art systems currently identified in its Initial Invalidity Contentions as one prior art source, see D.I. 164-1 at 20-21, is **GRANTED**.

2. Plaintiff's Motion to Compel Defendant to amend its Initial Invalidity Contentions for the '269 Patent to identify the specific references it is asserting for anticipation versus the specific references it is asserting for obviousness is **GRANTED.** Invalidity contentions that fail to "provide any hint as to which references may render the claims anticipated versus which references may render the claims obvious" fall short of meeting this standard. *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, 223 F. Supp. 3d 202, 205 (D. Del. 2016). Thus, for each limitation, Defendant's Initial Invalidity Contentions should specify which references it is asserting for anticipation and separately which references it is asserting for obviousness.

3. Plaintiff's Motion to Compel Defendant to identify the specific combinations of references it is asserting in support of its obviousness theory, including which claim elements Defendant alleges exist in any specific reference, is **GRANTED.** For each of its invalidity theories, Defendant should include supporting evidence. In support of its

obviousness theories in particular, Defendant's explanation should include identification of the claim element(s) disclosed by each reference in the combination.

4. Plaintiff's Motion to Compel Defendant to provide discovery on its inventorship defense is **DENIED**. Defendant asserted before the Court that it has produced all documents in its possession relevant to this defense and has identified three (3) prior employees with related information, and Plaintiff has deposed only one (1) of them. Thus, the Court is not convinced that Defendant's discovery is deficient.

5. Plaintiff's Motion to Compel Defendant to provide the factual and legal basis for its defenses is **GRANTED-IN-PART** and **DENIED-IN-PART**. The Court grants Plaintiff's Motion to Compel Defendant to provide the factual and legal basis for its standing defense. At this time, the Court will not compel Defendant to provide the factual and legal bases for its government sales and prosecution estoppel defenses since Defendant clarified before the Court that it expects to supplement its disclosures as to both defenses soon.

6. Defendant's Motion to Compel Plaintiff to provide a complete response to Defendant's Interrogatory No. 15 seeking the identity of and details related to all third-party litigation funders is **DENIED** without prejudice. The Court is not persuaded that standing is at issue since Plaintiff has already disclosed that, "[b]esides CleveMed, no person or entity has currently or had previously an ownership or financial interest in the Patents-in-Suit." D.I. 83 at 4 (citing Ex. 11, D.I. 83 at 131). Thus, standing cannot form the basis for a discovery request where, as here, "Defendant does not refer to any specific evidence or support showing that Plaintiff here does not have 'all rights, titles, and interests in the asserted patents' as Plaintiff claims." *Colibri Heart Valve LLC v. Medtronic CoreValve*

LLC, 2021 WL 10425630, at *3 (C.D. Cal. Mar. 26, 2021). Similarly, Defendant cannot base its request for litigation funding discovery on witness bias or credibility when it has given the Court no "specific, articulated reason to suspect bias or conflicts of interest." *See Nantworks, LLC v. Niantic, Inc.*, No. 20-cv-06262-LB, 2022 WL 1500011, at *2 (N.D. Cal. May 12, 2022). Finally, while this Court has previously held that materials discussing litigation funding *may* be relevant to the value of asserted patents, Defendant has not presented the Court with any reason to believe that such documents are relevant here. *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742-GBW, at ¶ 3 (D. Del. Apr. 18, 2023) (D.I. 1725). Plaintiff, on the other hand, asserts that no documents in its possession relate to the value of the asserted patents, and Defendant will be provided information regarding the value of each asserted claims through Plaintiff's damages expert report. Thus, the Court is not convinced at this time that there exists a substantial need to justify compelling litigation funding discovery.

7. Having resolved Plaintiff's Motions to Compel, the Court orders Defendant to amend its initial invalidity contentions by **November 10, 2023**.

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GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

EXHIBIT I

ORAL ORDER: The Court, having again reviewed the parties' briefing with regard to Plaintiffs' final lingering discovery dispute, (D.I. 307; D.I. 311; D.I. 317), addressed during the March 28, 2022 teleconference, and having reviewed Defendants' March 29, 2022 supplemental submission, (D.I. 329), hereby ORDERS as follows: (1) Plaintiffs' request that the Court compel Defendants to supplement Interrogatory No. 3 to confirm that they will not rely on any prior art other than the 41 identified references, absent a proper amendment, (D.I. 311 at 4), is DENIED. As Defendants note, (D.I. 317 at 4-5), this request appears to conflict with the Scheduling Order's May 26, 2022 deadline for final supplementation of all invalidity references, (D.I. 303 at 2).; and (2) With regard to Plaintiffs' remaining requests, (D.I. 311 at 4), they are GRANTED-IN-PART as follows. These requests are premised on Plaintiffs' assertion that Defendants' current response to Plaintiffs' Interrogatory No. 3 (which requests Defendants' contentions that the asserted claims of the patent-in-suit are invalid under 35 U.S.C. § 103), which in turn incorporates by reference Defendants' Joint Initial Invalidity Contentions (the "Initial Invalidity Contentions"), are unduly vague and insufficiently fulsome. (Id. at 3-4) The Court has reviewed the Initial Invalidity Contentions. In general, they provide real detail, including significant specificity as to: (a) the prior art references that could be a part of invalidity combinations, (see, e.g., Initial Invalidity Contentions at 54-114); (b) the portions of the prior art references that are relevant to Defendants' obviousness arguments, (see, e.g., id. at Appendix A); and (c) why a person of ordinary skill in the art might be motivated to combine the teachings of certain prior art references, (see id. at 128-31, 136-47). That said, the one area as to which the Court has sympathy for Plaintiffs' position is that in the Initial Invalidity Contentions, Defendants generally state that the asserted claims are obvious over many possible combinations of many different references, (see, e.g., id. at 132), which makes it difficult for Plaintiffs to know exactly which specific combinations are being asserted against them. On that score, Plaintiffs should get some relief. In terms of how and when that relief should be provided, the Court repeatedly suggested that if Plaintiffs were willing to narrow the number of asserted claims, then the Court could require Defendants to then cut down to a specific number of invalidity combinations by a date certain. But Plaintiffs did not seem particularly interested in that option during the teleconference. In light of this, and in light of the fact that the deadline for final invalidity contentions is coming up soon, the Court hereby ORDERS that by June 22, 2022, the date when Defendants' final invalidity contentions are due, Defendants shall: (a) identify in those final invalidity contentions the specific invalidity combinations they intend to rely upon (without the use of terms like "exemplary" and "and/or"); (b) provide fulsome detail regarding the obviousness arguments for those specific invalidity combinations; and (c) supplement their response to Interrogatory No. 3 by incorporating the final invalidity contentions into that response. Ordered by Judge Christopher J. Burke on 4/21/2022. (mlc) (Entered: 04/21/2022)

As of April 22, 2022, PACER did not contain a publicly available document associated with this docket entry. The text of the docket entry is shown above.

Astellas Pharma Inc. et al v. Sandoz Inc. et al
1-20-cv-01589 (DDE), 4/21/2022, docket entry 343